Policy	Drug(s)	Type of Change	Brief Description of Policy Change
new	Clolar (clofadribine)	n/a	n/a
new	Koselugo (selumetinib)	n/a	n/a
new	Mektovi (binimetinib)	n/a	n/a
new	Photofrin (porfimer)	n/a	n/a
new	Tepadina (thiotepa)	n/a	n/a
new	Tukysa (tucatinib)	n/a	n/a
UM ONC_1046	Bacillus Calmette-Guerin (bcg)	archived- add to UM ONC_1304 Generic Drugs	n/a
UM ONC_1072	MGF	Negative change	Add exclusion criteria: 5. Neupogen, Leukine, Zarxio, Nivestym, or Granix use within 7 days of Pegfilgrastim.
UM ONC_1133	Erbitux (Cetuximab)	Negative change	Add inclusion criteria: 3. Colorectal Cancer - b. The member has unresectable, advanced, or metastatic RAS wild-type and BRAF V600E mutation positive colorectal cancer and Erbitux (cetuximab) is being usedmay be used in combination with encorafenib after prior therapy in the metastatic setting. NOTE: Cetuximab + Encorafenib is NCH preferred L1 pathway for second-line or subsequent therapy in the metastatic setting.
UM ONC_1133	Erbitux (Cetuximab)	Negative change	Add exclusion criteria: 3. Pre-operative chemotherapy for potentially resectable liver metastases from KRAS/NRAS wild-type colorectal cancer

UM ONC_1180	Intravenous Immune Globulin (Ig) (IVIG)	Negative change	Add inclusion criteria: 2. Chronic Lymphocytic Leukemia (CLL) and Multiple Myeloma - Initial request: a documented history of frequent sino-bronchial, skin or other site infections; Conitnuation requests: i. The member has had ad coumented clinical benefit from IVIgG therapy, e.g. reduced incidence of infections OR ii. The member has a history of an increase in recurrent infections within the last 6 months OR iii. The IgG level ≤ 1,000 mg/dL within the last 4 weeks.
UM ONC_1180	Intravenous Immune Globulin (Ig) (IVIG)	Negative change	Add exclusion criteria: 1. For CLL/Multiple Myeloma/Acquired Hypogammaglobulinemia the dosing exceeds 400 mg/kg for each dose and the frequency of administration is more frequent than once every 28 days 2. For ITP, the dosing exceeds 400 mg/kg daily x 5 days or 1 gm/kg x 1-2 days

UM ONC_1194	Nexavar (sorafenib)	Negative change	Add inclusion criteria:2.Renal Cell Carcinoma (RCC)- a.The preferred tyrosine kinase inhibitor, per NCH Policy & NCH Pathway for advanced or metastatic RCC, is Cabometyx (cabozantinib) or Votrient (pazopanib); a.Nexavar (sorafenib) will be used as a single agent for recurrent or metastatic RCC in members who have disease progression, contraindications, or intolerance to prior Pazopanib AND Cabozantinib. 3.Hepatocellular Carcinoma (HCC)- a.The preferred agent, per NCH Policy & NCH Pathway, for unresectable or metastatic HCC are as follows: i.For first line treatment: Lenvima (Lenvatinib) ii.For subsequent treatment: Stivarga (regorafenib). b.Nexavar (sorafenib) will be used as a single agent in members with Child-Pugh Class A or B7 unresectable HCC, for patients who are intolerant to/contraindications to Lenvatinib

UM ONC_1194	Nexavar (sorafenib)	Positive change	(RCC) a. Nexavar (sorafenib) is being used for advanced RCC as first-line therapy as a single agent for relapsed or medically unresectable stage IV disease with any of the following: i. Predominant clear cell histology in selected members ii. Non-clear cell histology b. Subsequent therapy as a single agent for relapsed or medically unresectable stage IV disease with predominant clear cell histology in members who have progressed on prior first-line therapy, including cytokine or tyrosine kinase therapy. Hepatocellular Carcinoma (HCC) a. Nexavar (sorafenib) is being used for unresectable HCC as treatment as a single agent for members (Child-Pugh Class A or B7) AND with ONE of the following: i. Are non-transplant candidates with unresectable disease ii. Are inoperable by performance status or co-morbidity (local disease or local disease with minimal extra-hepatic disease only) iii. Have extensive liver tumor burden or metastatic disease. 3. Thyroid Carcinoma
UM ONC_1194	Nexavar (sorafenib)	Negative change	Add exclusion criteria: 1. Off-label indications for Nexavar (sorafenib) in soft tissue sarcoma.

UM ONC_1197	Sutent (sunitinib)	Negative change	Add inclusion criteria: 2. Renal cell carcinoma (RCC) a. NOTE: The preferred tyrosine kinase inhibitor, per NCH policy and pathway for advanced or metastatic RCC, is Cabometyx (cabozantinib) or Votrient (pazopanib). Please refer to the NCH Pathway document 3. Gastrointestinal stromal tumor (GIST) a. Sutent (sunitinib) will be used as a single agent in members who have disease progression on OR, contraindications to, OR intolerance to Imatinib. 4. Pancreatic Neuroendocrine tumor (PNET) a. NOTE: The preferred agents, per NCH Policy and pathway, for first line and subsequent treatment of pancreatic neuroendocrine tumor are Everolimus and Sunitinib. b. Sutent (sunitinib) will be used as a single agent for unresectable or metastatic pancreatic neuroendocrine tumor.

UM ONC_1197	Sutent (sunitinib)	Negative change	Add inclusion criteria: 2. Renal cell carcinoma (RCC) a. NOTE: The preferred tyrosine kinase inhibitor, per NCH policy and pathway for advanced or metastatic RCC, is Cabometyx (cabozantinib) or Votrient (pazopanib). Please refer to the NCH Pathway document 3. Gastrointestinal stromal tumor (GIST) a. Sutent (sunitinib) will be used as a single agent in members who have disease progression on OR, contraindications to, OR intolerance to Imatinib. 4. Pancreatic Neuroendocrine tumor (PNET) a. NOTE: The preferred agents, per NCH Policy and pathway, for first line and subsequent treatment of pancreatic neuroendocrine tumor are Everolimus and Sunitinib. b. Sutent (sunitinib) will be used as a single agent for unresectable or metastatic pancreatic neuroendocrine tumor.

UM ONC_1197	Sutent (sunitinib)	Positive change	carcinoma a. Sutent (sunitnib) is being used as ONE of the following: i. First or subsequent line therapy as a single agent for relapsed or medically unresectable stage IV disease with predominant clear cell or in members with non-clear cell histology. 2. Gastrointestinal stromal tumor (GIST) a. Sutent (sunitnib) is being used after progression on or intolerance to imatinib. 3. Pancreatic Neuroendocrine tumor (PNET) a. The member has pancreatic endocrine tumor and Sutent (sunitnib) is being used for unresectable, locally advanced, or metastatic disease 4. Soft tissue sarcoma a. Sutent (sunitnib) is being used as any of the following: i. As a single agent for angiosarcoma ii. As a single-agent therapy for the treatment of solitary fibrous tumor and hemangiopericytoma. 5. Thyroid carcinoma a. The member has follicular, papillary, or Hurthle cell thyroid cancer and Sutent (sunitnib) is being consider for treatment of clinically progressive or symptomatic iodine-refractory recurrent/metastatic disease.

UM ONC_1232	Stivarga (regorafenib)	Positive change	Remove inclusion criteria: 2. Colon and Rectal Cancers a) Second or third line therapy to used in treatment of advanced/metastatic ii. Has ECOG performance 0-1 AND 3. GIST- disease progression, contraindications, or intolerance to Imatinib OR Sunitinib. 4. Hepatocellular Carcinomabiliary Cancers- Stivarga (regorafenib) will be used as a single agent in members with Child-Pugh Class A unresectable HCC, as second or subsequent line of therapy.
UM ONC_1232	Stivarga (regorafenib)	Negative change	Add inclusion criteria: 3. GIST - Stivarga (regorafenib) will be used as a single agent for the treatment of GIST in members who have disease progression, contraindications, or intolerance to Imatinib AND Sunitinib. 4. Hepatocellular Carcinoma - Stivarga (regorafenib) will be used as a single agent in members with Child-Pugh Class A unresectable HCC, as second or subsequent line of therapy.

UM ONC_1232	Stivarga (regorafenib)	Positive change	Remove exclusion criteria: 1. Member has any of the following: a. Baseline severe hepatic impairment (Child-Pugh class C) or b. AST/ALT elevations during therapy greater than 3X ULN with concurrent bilirubin level elevations greater than 2X ULN or c. AST or ALT more than 20 times the upper limit of normal (ULN) at any time or d. AST or ALT more than 5 times ULN despite dose reduction to 120 mg.
UM ONC_1239	Pomalyst (pomalidomide)	Negative change	Add inclusion criteria: a. NOTE: The preferred immunomodulatory agent, per NCH policy and pathway, is LENALIDOMIDE over Pomalidomide orThalidomide. a. The member has relapsed or refractory multiple myeloma and Pomalyst (pomalidomide) is being used as a single agent ± dexamethasone
UM ONC_1239	Pomalyst (pomalidomide)	Negative change	Add exclusion criteria: 1. Disease progression while treceiving Pomalyst (pomalidomide) containing regimen.
UM ONC_1262	Imbruvica (ibrutinib)	Negative change	Add inclusion criteria: 2. Mantle Cell Lymphoma (MCL) a. The member has a diagnosis of relapsed or refractory MCL that has failed or has progressed on first line chemo-immunotherapy AND b. Imbruvica (ibrutinib) will be used in combination with rituximab

UM ONC_1262	Imbruvica (ibrutinib)	Positive change	Add inclusion criteria: 2. Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) a. Imbruvica(ibrutinib) use as a single agent is supported for initial and subsequent therapy for all prognostic categories of CLL/SLL 3. Waldenström's Macroglobulinemia/Lymphoplasmacytic Lymphoma- Imbruvica (ibrutinib) will be used in combination with rituximab 4. Nodal Marginal Zone Lymphoma -b. Imbruvica (ibrutinib) will be used as a single agent as second-line or subsequent therapy following an anti-CD20 based therapy (e.g. rituximab +/- chemotherapy).
UM ONC_1262	Imbruvica (ibrutinib)	Negative change	Add exclusion criteria: 1. Disease progression while receiving Imbruvica/ Imbruvica containing regimen or another BTK inhibitor/ BTK inhibitor containing regimen, e.g. Acalabrutinib or Zanubrutinib.
UM ONC_1263	Keytruda (pembrolizumab)	Positive change	Remove inclusion criteria:a. NSCLC first line therapy: both tissue biopsy and liquid biopsy are unsuccessful in providing sufficient diagnostic material for testing for the above 3 markers; c. In combination with pemetrexed and platinum chemotherapy in members with non-squamous histology if EGFR, ALK, or ROS1 genomic alterations are ~~unknown~~, regardless of the PD-L1 level

UM ONC_1263	Keytruda (pembrolizumab)	Negative change	Add inclusion criteria: 8.Gastric Cancer or Esophageal and Esophagogastric Junction Cancers a.The member has unresectable locally advanced, recurrent, or metastatic instability-high (MSI-H) /mismatch repair deficient OR PD-L1 positive gastric, esophageal, or esophagogastric junction cancers AND b.For esophageal, or esophagogastric junction cancers: Keytruda (pembrolizumab) is being usedwill be used as a single agent, as second line therapy if PD-L1 is ≥10 % and third line therapy if PD-L1 is ≥1% regardless of PD-L1 status. c.For gastric cancers: Keytruda (pembrolizumab) will be used as a single agent as third line therapy if PD-L1 is ≥1%.
UM ONC_1264	Zydelig (idelalisib)	Negative change	Add inclusion criteria: Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL)/Follicular NHL a.NOTE: Zydelig (idelalisib) is NOT recommended as an appropriate therapeutic agent for either CLL or for Follicular Lymphoma per NCH Policy and NCH Pathway because the risk of severe toxicities outweighs the benefits.

UM ONC_1264	Zydelig (idelalisib)	Positive change	Remove inclusion criteria: 1. Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) a. The member has a diagnosis of relapsed or refractory CLL/SLL AND b. The member is not a candidate or cannot tolerate standard cytotoxic chemotherapy (i.e. fludarabine, cyclophosphamide, and rituxumab (FCR); bendamustine and rituximab (BR); or pentostatin, cyclophosphamide, and rituximab (PCR)) 2. Follicular Lymphoma and Nodal Marginal Zone Lymphoma a. The member has a diagnosis of relapsed follicular , Nodal marginal zone gastric and non-gastric MALT, or splenic marginal zone lymphoma
UM ONC_1264	Zydelig (idelalisib)	Negative change	Add exclusion criteria: 1. Disease progression with Idelalisib/Idelalisib containing regimen or another PI3K inhibitor/PI3K inhibitor containing regimen (i.e. duvelisib).
UM ONC_1280	Darzalex (daratumumab)	Negative change	Add inclusion criteria: NOTE: The preferred anti-CD38 agent for Multiple Myeloma,, per NCH policy and NCH pathway, is DARATUMUMAB over Isatuximab.
UM ONC_1280	Darzalex (daratumumab)	Negative change	Add inclusion criteria:ii. Daratumumab + Bortezomib + Steroid (DVd) as initial therapy for relapsed/refractory disease
UM ONC_1281	Empliciti (elotuzumab)	Negative change	Add inclusion criteria:2. Multiple Myeloma Please refer to the NCH Pathway document for preferred regimens per NCH Pathway for relapsed/refractory myeloma.

UM ONC_1281	Empliciti (elotuzumab)	Positive change	Remove inclusion criteria: 2. Multiple Myeloma a. Empliciti (elotuzumab) is used in combination with lenalidomide/bortezomib and dexamethasone. i. Members with prior treatment with Lenalidomide/bortezomib will be permitted if: A. Best response achieved was ≥Partial Response (PR) AND ii. Member was not refractory AND iii. Member did not discontinue due to a Grade ≥3 related adverse event AND iv. Member did not receive more than 9 cycles of Lenalidomide and had at least 9 months between the last dose of Lenalidomide and progression OR b. When used in combination with pomalidomide must have responded to previous treatment with proteosome inhibitor or lenalidomide, or both, but progressed within 6 months AND i. The patient must have received 1 to 3 prior lines of therapies for the treatment of multiple myeloma. AND ii. Member must have documented progression following their most recent therapy.
UM ONC_1304	Generic Drugs	Positive change	Add inclusion criteria: added BCG to the policy; BCG policy will be archived

UM ONC_1313	Alunbrig (brigatinib)	Negative change	Add inclusion criteria: 2.Non-Small Cell Lung Cancer (NSCLC) NOTE: The preferred targeted therapies, per NCH policy and pathway, for recurrent, advanced, or metastatic ALK+ NSCLC are as follows: i.First-line therapy: Alectinib ii.Subsequent-line therapy: Crizotinib or Brigatinib (if failed Crizotinib). Brigatinib may be used as a single agent for members for ALK + metastatic/recurrent Non Small Cell Lung Cancer, when the disease has progressed on prior crizotinib therapy
UM ONC_1313	Alunbrig (brigatinib)	Positive change	Remove exclusion criteria: 1.Disease progression with ALK Inhibitors other than crizotinib (i.e. alectinib, or ceritinib).
UM ONC_1314	Imfinzi (durvalumab)	Negative change	Add inclusion criteria:2.Urothelial Carcinoma NOTE: Per NCH policy and NCH pPathway the checkpoint inhibitor of choice,s for subsequent therapy of metastatic/recurrent urothelial carcinomais, KeytrudaKeytruda is the preferred checkpoint inhibitor rather than over Opdivo, Tecentriq, Bavencio or Imfinzi. Please refer to the NCH Pathway document.

UM ONC_1315	Imfinzi (durvalumab)	Positive change	Remove inclusion criteria:2.Urothelial Carcinoma a. The member has locally advanced, metastatic, or recurrent urothelial carcinoma and Imfinzi (durvalumab) will be used as a single agent following disease progression during or after platinum-based chemotherapy
UM ONC_1314	Imfinzi (durvalumab)	Positive change	Remove exclusion criteria: 2.Urothelial Carcinoma b.The member has locally advanced, metastatic, or recurrent urothelial carcinoma and Imfinzi (durvalumab) is being usedwill be used as a single agent following disease progression during or after platinum-based chemotherapy.
UM ONC_1314	Imfinzi (durvalumab)	Positive change	Remove exclusion criteria: 5.3.Non-Small Cell Lung Cancer (NSCLC) a.Imfinzi (durvalumab) is being usedwill be used as consolidation therapy, after completion of definitive chemoradiation, in members with unresectable stage II disease
UM ONC_1314	Imfinzi (durvalumab)	Negative change	Add inclusion criteria: 4.Small Cell Lung Cancer (Extensive Stage) b.NOTE: Per NCH Policy and NCH Pathway the preferred checkpoint inhibitor for first line therapy of Extensive Stage Small Cell Lung Cancer is Tecentriq. Please refer to the NCH Pathway document

UM ONC_1314	Imfinzi (durvalumab)	Positive change	Remove exclusion criteria: 1. Off-label indications for Imfinzi (durvalumab) in small cell lung cancer. shall be reviewed for appropriateness per National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or other compelling medical literature publications.
UM ONC_1314	Imfinzi (durvalumab)	Negative change	Add exclusion criteria: 4. Members with locally advanced non-small cell lung cancer (NSCLC) with disease progression after chemoradiation.
UM ONC_1335	Braftovi (encorafenib)	Unconsolidate policy	Unconsolidate UM ONC_1335 Braftovi™ (encorafenib) and Mektovi™ (binimetinib) to UM ONC_1335 Braftovi™ (encorafenib) and new policy Mektovi™ (binimetinib)
UM ONC_1335	Braftovi (encorafenib)	Negative change	Add inclusion criteria:2. Melanoma NOTE: The preferred BRAF and MEK inhibitor combination regimen, per NCH policy and pathway, for unresecatble/metastatic BRAF mutation positive melanoma is the combination of Cobimetinib + Vemurafenib over Binimetinib + Encorafenib.

UM ONC_1335	Braftovi (encorafenib)	Positive change	Remove inclusion criteria: 2.Melanoma The member has BRAF V600E or V600K activating mutation and unresectable or metastatic melanoma AND. a.Braftovi (encorafenib) will be used in combination with and Mektovi (binimetinib). is being used as combination therapy AND b.a.The member has BRAF V600E or V600K mutation and unresectable or metastatic melanoma.
UM ONC_1335	Braftovi (encorafenib)	Positive change	Remove exclusion criteria: 2.Concurrent use with other BRAF or MEK inhibitors. 3.Member with wild-type BRAF melanoma or colorectal cancer.
UM ONC_1335	Braftovi (encorafenib)	Negative change	Add exclusion criteria:1.Disease progression with prior BRAF inhibitor, either as a single agent or as part of a combination regimen
UM ONC_1335	Braftovi (encorafenib)	Positive change	Remove exclusion criteria: 4.2.Dosing exceeds single dose limit of Mektovi (binimetinib) 45 mg. 5.3.Treatment exceeds the maximum limit of Mektovi 90 (15 mg) tablets per month.
UM ONC_1344	Poteligeo (mogamulizumab - kpkc)	Negative change	Remove inclusion criteria: 1.T-Cell Lymphomas/Leukemia A.As second-line therapy, with intention to proceed to high-dose therapy/allogeneic stem cell rescue OR B.As subsequent therapy to HDT/ASCR as a single agent for non-responders to first-line therapy for acute or lymphoma subtypes.

UM ONC_1344	Poteligeo (mogamulizumab - kpkc)	Negative change	Add exclusion criteria: 1.Off-label indications for Poteligeo (mogamulizumab-kpkc) in T-Cell leukemia/lymphoma. 3.Concurrent use with other systemic therapies (may be used with skin directed therapy or radiation therapy).
UM ONC_1344	Poteligeo (mogamulizumab - kpkc)	Positive change	Remove exclusion criteria: 3.Member has a known active infection or autoimmune disease.
UM ONC_1281	Empliciti (elotuzumab)	Positive change	Remove exclusion criteria: 1.Members with non-secretory or oligo-secretory or serum free light-chain only myeloma. 2.Members with active plasma cell leukemia. 3.Members with Known Human immunodeficiency virus (HIV) infection or active hepatitis A, B, or C.

UM ONC_1331	Calquence (acalabrutinib)	Negative change	Add inclusion criteria: 1. Mantle Cell Lymphoma (MCL) a. NOTE: The preferred Bruton tyrosine kinase (BTK) inhibitor regimen, per NCH policy, is IBRUTINIB over Acalabrutinib or Zanubrutinib. 2. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma a. NOTE: The preferred Bruton tyrosine kinase (BTK) inhibitor agentregimen, per NCH policy and NCH Pathway, is IBRUTINIB over Acalabrutinib, except when the member is intolerant to or has a contraindication to Ibrutinib. Acalabrutinib may be used, as a single agent, for first line or subsequent line therapy of CLL/SLL in patients who are intolerant to or have a contraindication to Ibrutinib

UM ONC_1331	Calquence (acalabrutinib)	Positive change	Remove inclusion criteria: 1. Mantle Cell Lymphoma (MCL) The member has a diagnosed of stage I-II disease, aggressive stage II bulky, III, or IV disease, or symptomatic indolent stage II bulky, III, or IV disease MCL and relapased or refractory MCL and has failed at least one prior chemoimmunotherapy AND b. Calquence (acalabrutinib) will be used as a single agent is being used as the following: i. Single agent therapy AND ii. After partial response to induction therapy OR iii. For relapsed, refractory, or progressive disease. 2. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma a. The member has relapsed or refractory CLL/SLL with or without del(17p)/TP53 mutation AND b. Calquence (acalabrutinib) is being will be used as a single agent. for relapsed or refractory disease with or without del(17p)/TP53 mutation.

UM ONC_1331	Calquence (acalabrutinib)	Negative change	Add exclusion criteria: 1. Disease progression while receiving Acalabrutinib/Acalabrutinib-containing egimen or while receiving another BTK inhibitor (e.g.i.e. iIbrutinib or Zanubrutinib) 2. Concurrent use with an anti-CD20 antibody including Rituximab/Rituximab Hycela/Rituximab Biosimilars/Gazyva (Per NCH Policy and NCH Pathway single agent Acalabrutinib is as effective as Acalbrutinib + Gazyva/other anti-CD 20 antibody
UM ONC_1347	Lorbrena (lorlatinib)	Negative change	Add inclusion criteria:1.Non-Small Cell Lung Cancer (NSCLC) NOTE: The preferred targeted therapies, per NCH policy and pathway, for recurrent, advanced, or metastatic ALK positive NSCLC are as follows: i.First-line therapy: Alectinib ii.Subsequent-line therapy: Crizotinib or Brigatinib (if failed Crizotinib). b.The member has recurrent or metastatic ALK positive NSCLC AND c.Disease progression, contraindications, or intolerance to Alectinib AND Brigatinib AND d.Lorbrena (lorlatinib) will be used as a single agent.

UM ONC_1347	Lorbrena (lorlatinib)	Positive change	Remove inclusion criteria: 1.Non-Small Cell Lung Cancer (NSCLC)- Following disease progression on Xalkori (crizotinib) and at least on other ALK inhibitor OR ii.If disease has progressed on alectinib or ceritinib as the first ALK inhibitor therapy for metastatic disease.
UM ONC_1347	Lorbrena (lorlatinib)	Positive change	Remove exclusion criteria: 2.Use in the first line for metastatic disease.
UM ONC_1349	Talzenna (talazoparib)	Negative change	Add inclusion criteria: 1.Breast Cancer NOTE: The preferred PARP inhibitor, per NCH policy andNCH pathway, is OLAPARIB for recurrent or metastatic, germline BRCA 1/2 mutation positive, and HER2 negative breast cancer. Please refer to the NCH Pathway document.
UM ONC_1349	Talzenna (talazoparib)	Positive change	Remove inclusion criteria: 1.Breast Cancer iv.Member has received prior chemotherapy for metastatic disease but no more than 3 prior chemotherapy regimens for locally advanced and/or metastatic disease.
UM ONC_1349	Talzenna (talazoparib)	Positive change	Remove exclusion criteria: 2.Concurrent use with other chemotherapy.
UM ONC_1349	Talzenna (talazoparib)	Negative change	Add exclusion criteria: Disease progression on a Talazoparib containing regimen
UM ONC_1360	Piqray (alpelisib)	Negative change	Add inclusion criteria: Piqray is not a preferred agent per NCH Policy and NCH Pathway.Please refer to the NCH Pathway document to see the preferred regimens/agents for first and subsequent lines of therapy in metastatic ER/PR positive breast cancer.

UM ONC_1360	Piqray (alpelisib)	Positive change	Remove inclusion criteria:a.Breast cancer a. The member has recurrent/metastatic, hormone receptor positive, and PIK3CA-mutation positive, and HER2 negative breast cancer AND b.If female, the member is postmenopausal AND c.The member has disease progression, intolerance, or contraindications to prior endocrine therapy
UM ONC_1360	Piqray (alpelisib)	Positive change	Remove exclusion criteria: 3.Member with any of the following: a.Child pugh score B or C b.An established diagnosis of diabetes mellitus type I or not controlled type II c.History of pancreatitis.
UM ONC_1363	Nubeqa (darolutamide)	Negative change	Add inclusion criteria: 1.Prostate Cancer NOTE: Per NCH policy and pathway for metastatic castration-sensitive prostate cancer, the preferred agent is generic Abiraterone over brand name Zytiga. NOTE: For NON-metastatic castration-resistant prostate cancer, the preferred agents are Enzalutamide/Apalutamide over Darolutamide.

UM ONC_1363	Nubeqa (darolutamide)	Positive change	Remove exclusion criteria: 1. Disease progression with PI3K or mTOR inhibitor (e.g. everolimus). 2. Concurrent use with other chemotherapy. 3. Member with any of the following: a. Child pugh score B or C b. An established diagnosis of diabetes mellitus type I or not controlled type II c. History of pancreatitis.
UM ONC_1363	Nubeqa (darolutamide)	Positive change	Remove inclusion criteria: 1. Prostate Cancer b. The member has M0 castration-resistant prostate cancer AND c. Nubeqa (darolutamide) is being used as secondary hormone therapy in combination with an LHRH agonist or antagonist AND d. Member has PSA doubling time (PSADT) ≤ 10 months, PSA > 2 ng/mL, and with no or minimal symptoms AND e. ECOG performance status of 0-1 AND f. Has adequate renal (creatinine ≤ 2.0 x ULN.), hepatic (ALT and/or AST ≤ 2.5 x ULN, total bilirubin ≤ 1.5 x ULN, and hematopoietic function (Hgb ≥ 9.0 g/dl, ANC ≥ 1500/µl, PLT ≥ 100,000/µl).
UM ONC_1363	Nubeqa (darolutamide)	Negative change	Add exclusion criteria: 1. Disease progression with Nubeqa containing regimen or another Androgen Receptor Inhibitor (e.g. Enzalutamide or Apalutamide).

UM ONC_1363	Nubeqa (darolutamide)	Positive change	Remove exclusion criteria: 2. Prior treatment with estrogens or 5-α reductase inhibitors, androgen receptor inhibitors, CYP17 enzyme inhibitor, chemotherapy, or immunotherapy. 3. History of stroke, myocardial infarction, severe/unstable angina pectoris, coronary/peripheral artery bypass graft, congestive heart failure NYHA Class III or IV, or uncontrolled hypertension.
UM ONC_1365	Xpovio (selinexor)	Negative change	Add inclusion criteria: 1. Multiple MyelomaNOTE: Selinexor is not recommended per NCH Policy or NCH Pathway at this time. Please refer to the NCH Pathway document for recommended therapies for Myelom

UM ONC_1365	Xpovio (selinexor)	Positive change	Remove inclusion criteria: 1.2. Multiple Myeloma a. The member has relapsed or refractory multiple myeloma AND b. The member has received four anti-MM prior regimens ANDwith no history ≥ Grade 3 drug related toxicities AND c. Whose disease is refractory to at least two proteasome inhibitors (bortezomib, and carfilzomib, ixazomib), at least two immunomodulatory agents (lenalidomide, and pomalidomide, thalidomide), and an anti-CD38 monoclonal antibody (daratumumab or isatuximab) AND d. Has adequate renal (creatinine ≤ 2.0 x ULN.), hepatic (ALT and/or AST ≤ 2.5 x ULN, total bilirubin ≤ 1.5 x ULN, and hematopoietic function (Hgb ≥ 9.0 g/dl, ANC ≥ 1500/µl, PLT ≥ 100,000/µl) AND e. ECOG performance status 0-2.
UM ONC_1365	Xpovio (selinexor)	Positive change	Remove exclusion criteria: 2. Concurrent use with radiation, chemotherapy, or immunotherapy

UM ONC_1374	Balversa (erdafitinib)	Negative change	Add inclusion criteria: 2.Urothelial Carcinoma NOTE: The preferred agents, per NCH policy and pathway, for subsequent line advanced/metastatic urothelial carcinoma are single agents GEMCITABINE or PEMBROLIZUMAB (if failed prior platinum based chemotherapy). a.ii.iii.If ineligible for platinum containing therapy, the member had disease progression on prior Gemcitabine -based chemotherapy AND disease progression on Check Point Inhibitor (e.g. atezolizumab, avelumab, durvalumab, nivolumab, or pembrolizumab)
UM ONC_1374	Balversa (erdafitinib)	Negative change	Add exclusion criteria: 1. Lack of test results confirming a FGFR 3 or FGFR 2 genomic alteration in the tumor tissue
UM ONC_1374	Balversa (erdafitinib)	Positive change	Remove exclusion criteria: 3.Member has uncontrolled cardiovascular disease or persistent phosphate level greater than upper limit of normal (ULN).
UM ONC_1376	Oxbryta (voxelotor)	Negative change	Add inclusion criteria: 1.Sickle Cell Disease a.Oxbryta (voxelotor) is being will be used in adult members with ALL of the following: i.Sickle cell disease and prior use and failure of Hydroxyurea at the optimal dose for at least 3 months

UM ONC_1376	Oxbryta (voxelotor)	Positive change	Remove inclusion criteria: ii. opioids, or parenteral NSAIDs, acute chest syndrome, hepatic sequestration, splenic sequestration, and priapism AND iv. If receiving Hydroxyurea, dose of hydroxyurea must be stable for at least 3 months.
UM ONC_1376	Oxbryta (voxelotor)	Positive change	Remove inclusion criteria: ii. opioids, or parenteral NSAIDs, acute chest syndrome, hepatic sequestration, splenic sequestration, and priapism AND iv. If receiving Hydroxyurea, dose of hydroxyurea must be stable for at least 3 months.
UM ONC_1376	Oxbryta (voxelotor)	Negative change	Add exclusion criteria: 1. Inadequate clinical improvement with Oxbryta (voxelotor).